



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SPOR Communication & training update

EU IDMP/SPOR Task Force, 20 October 2017

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1. Update on SPOR training development activities
2. Training approach
3. Training curriculum
4. Training materials
5. Engagement with the SPOR change network
6. Upcoming communications / events

Priorities for SPOR training development:

1. Support user on-boarding for OMS and RMS.
 2. Support use of RMS as replacement for EUTCT (*EUTCT maintained for Substance lists*)
 3. Support integration of eAF with SPOR data services.
- **Target audience** includes SPOR users from **NCAs, Industry,** and **EMA.**
 - Training for substance and product data will follow as part of SMS and PMS project delivery.
 - RMS and OMS user training material will be available freely via public channels.

Review of Training Development



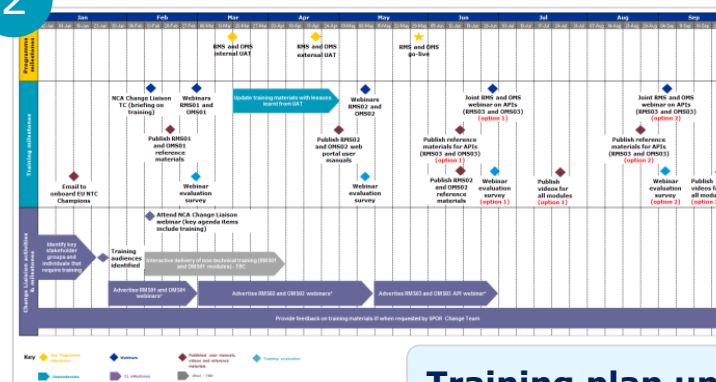
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1 LMS & OMS Training Curriculum

Ref.	Module Title	Module Description
RMS02	Viewing RMS Data	Data available from RMS List of lists, list of terms. Searching for RMS data Terms histories and versioning Languages and translations
RMS03	Working with RMS	Requesting new terms and lists Requesting updates to terms and lists Requesting removal of terms Managing the status of change requests
RMS04	RMS Additional Features	Subscribing to lists Change notifications Term tagging Exporting RMS data
RMS05	RMS Translations	Translations overview Term translations Bulk translations
OMS01	OMS Overview	OMS data services and benefits overview Integration with regulatory procedures Accessing OMS OMS-specific operating model Working with change requests

Training curriculum review & update

2



Training plan updates

3



EU NTC engagement

4



Create training materials

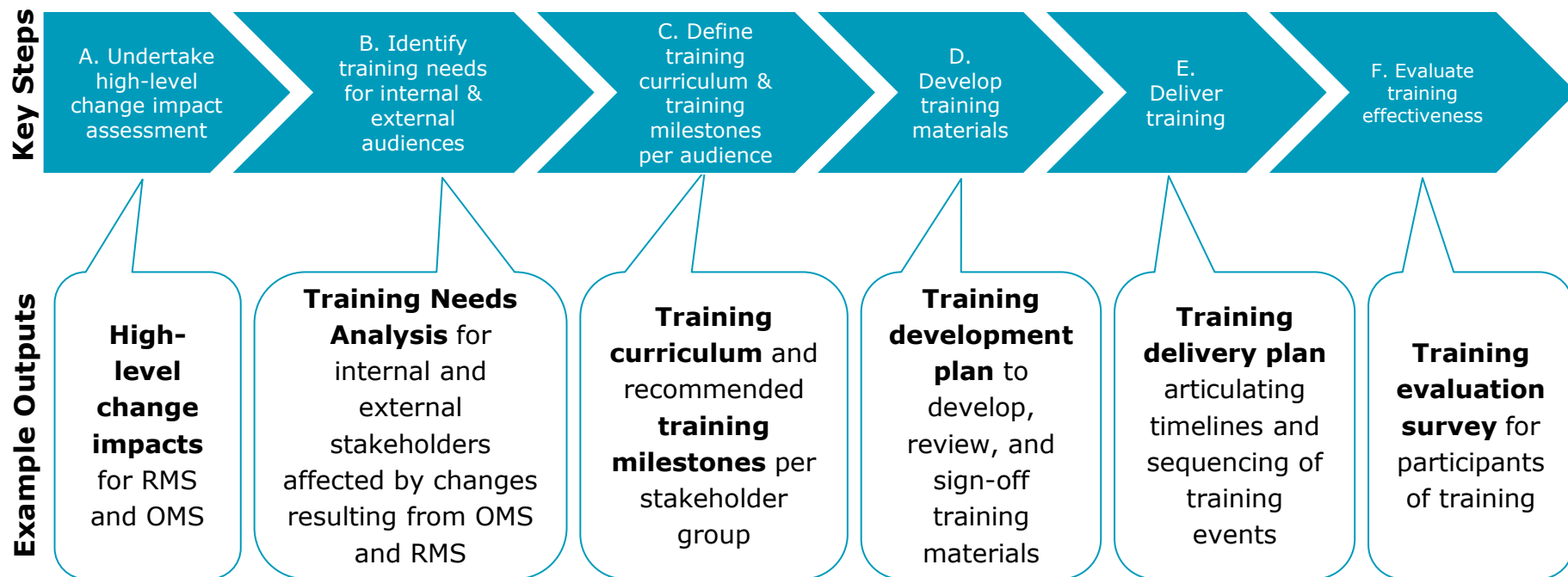
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Change Liaisons engagement

Recap Training Approach

- Our approach for SPOR training involves identification of change impacts resulting from OMS and RMS deployment.
- Analysis completed of the training needs arising for key stakeholder groups.
- Development of the SPOR training curriculum supports these training needs.
- Publication of training materials will be followed by evaluation in order to assess the effectiveness of the training with a view to improving content for future delivery.



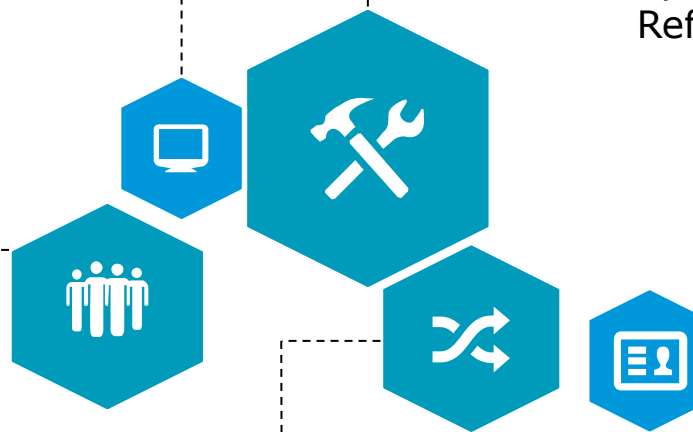
SPOR data is accessible via **web interface** and **API**

New process for Industry and NCAs to register and update Organisations and Referential data

A specialised team of **EMA Data Stewards** will manage SPOR data and provide support to stakeholders

New **data management** approaches for Industry, NCAs, and the EMA

List of **Organisations** and **Referentials** for use by stakeholders (controlled lists and terms)





- Modular approach to developing the SPOR training curriculum.
- Focus on core functionality of RMS and OMS.
- Mixture of documents, videos, and PowerPoint presentations.
- Detailed guidance available from the RMS & OMS user manuals.
- Training materials to be available publically for SPOR users without restrictions.

1. User manuals & reference documents provide detailed guidance for the RMS & OMS operating models, and which support technical training. Accessible via the [SPOR portal](#).

- RMS manual
- OMS manual
- User registration

2. Videos provide targeted, concise training modules for key topics. Available to view on-demand by all SPOR users.



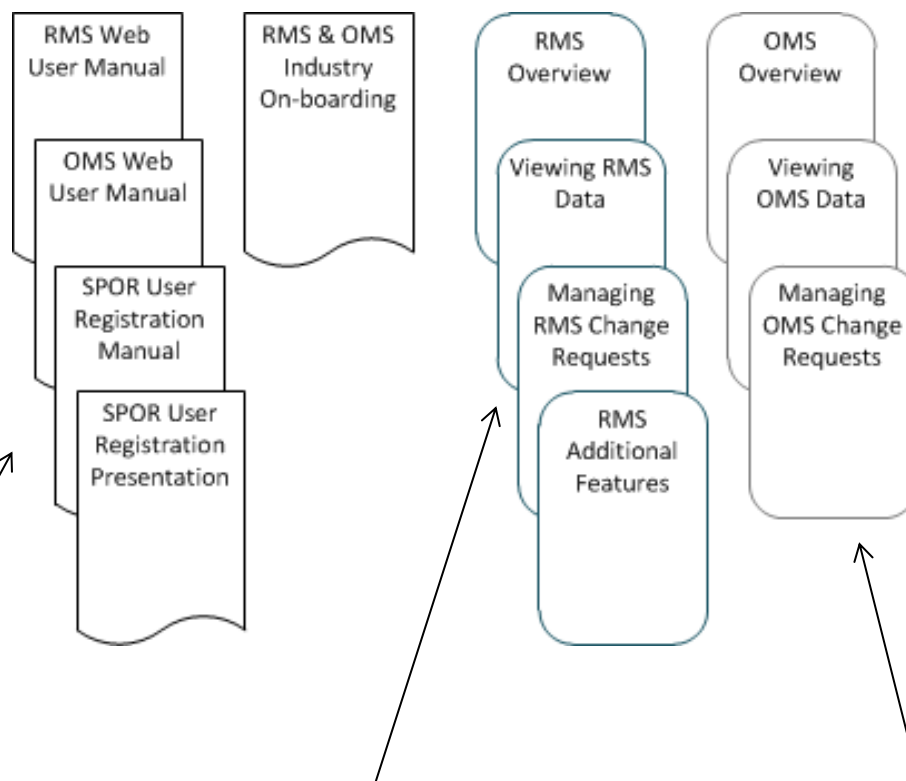
3. Presentations & Leaflets that support the videos. These focus on summarising content and signposting the detailed reference materials available on the SPOR portal and EMA website.

4. Webinars for NCA Change

Liaisons engage interactively with NCA audience across the EU regulatory network.

Also provides a forum for Q&As.

5. Live demonstrations may be used only for very specific training needs and is dependent upon resource availability.



SPOR documentation

RMS Web User manual
OMS Web User manual
RMS & OMS Industry On-boarding
SPOR User Registration manual
SPOR User Registration presentation

RMS training modules

RMS01 Overview of RMS
RMS02 Viewing RMS Data
RMS03A Term Change Requests
RMS03B List Change Requests

RMS03C Managing Change Requests

RMS04 Additional RMS Features

OMS training modules

OMS01 Overview of OMS
OMS02 Viewing OMS Data
OMS03 OMS Change Requests



- RMS videos currently in post-production; OMS videos due by the end of October 2017.
- Additional material and documentation available via the SPOR portal.
- Will be published via YouTube on the [@emainfo](#) channel.
- Announcements direct to Change Liaisons.



- Maintain links between SPOR programme and the Change Liaisons.
- Make available publically training materials to support all SPOR users.
- Engage with EU NTC Training Champions and the EU NTC (for NCAs)

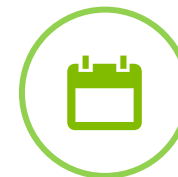
1. SPOR training course materials

Access to publically-available training materials will be via the @emainfo YouTube channel. User documentation available from the SPOR web portal.



2. Promoting SPOR training

SPOR training will feature in future communications to Industry Change Liaisons, including course contents and availability.



3. Industry Change Liaison support

Feedback on training courses can be sent directly to the SPOR Change Team. Training-related events will be included in the SPOR communications plan.



Upcoming communications / events



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2017				2018
	Oct	Nov	Dec	Jan
OMS & RMS related Milestones	<p>RMS & OMS Release 2.2 16 Oct</p>		<p>RMS & OMS Release 2.3 date tbc</p>	<p>eAF integration with OMS 15 Dec</p>
	<p><i>Expansion of the OMS dictionary</i></p>			
			<p>25.12 - 02.02 EMA is closed</p>	
Comms/ events	<p>Announce RMS/OMS release 2.2 16 Oct</p>		<p>Announce RMS /OMS release 2.3 Date tbc</p>	<ul style="list-style-type: none"> - Announce start of Industry on-boarding - eAF /OMS integration <p>15 Dec</p>
	<p>Industry Super User Registration webinar 4 Oct</p>	<p>Webinar - Process to request access to SPOR API 27 Nov</p>	<p>Webinar using OMS, RMS data in eAF 28 Nov</p>	
	<p>RMS online training videos</p>			
	<p>OMS online training videos</p>		<p>Webinar (Q&A format)</p> <ul style="list-style-type: none"> - Using OMS, RMS data in eAF - SPOR user registration <p>7 Dec</p>	



Topic: Process to request access to SPOR API

When: 27 November 2017, 14.00 – 15.30 London Time

Format: webinar

Audience: Technical (industry and NCAs)

Virtual room capacity: 100

DRAFT agenda:

- Process for requesting access to SPOR API
- Technical information around integration patterns, implementation tips, usage of mock-up services, how to read the specification
- Q&A - we will ask for questions to be submitted in advance to the webinar so that technical colleagues can prepare the responses
- Signpost the relevant documents



Topic: Using OMS and RMS data in eAF

When: 28 November 2017, 14.00 – 16.00 London Time

Format: webinar

Audience: SPOR change liaisons, regulatory (users of eAF)

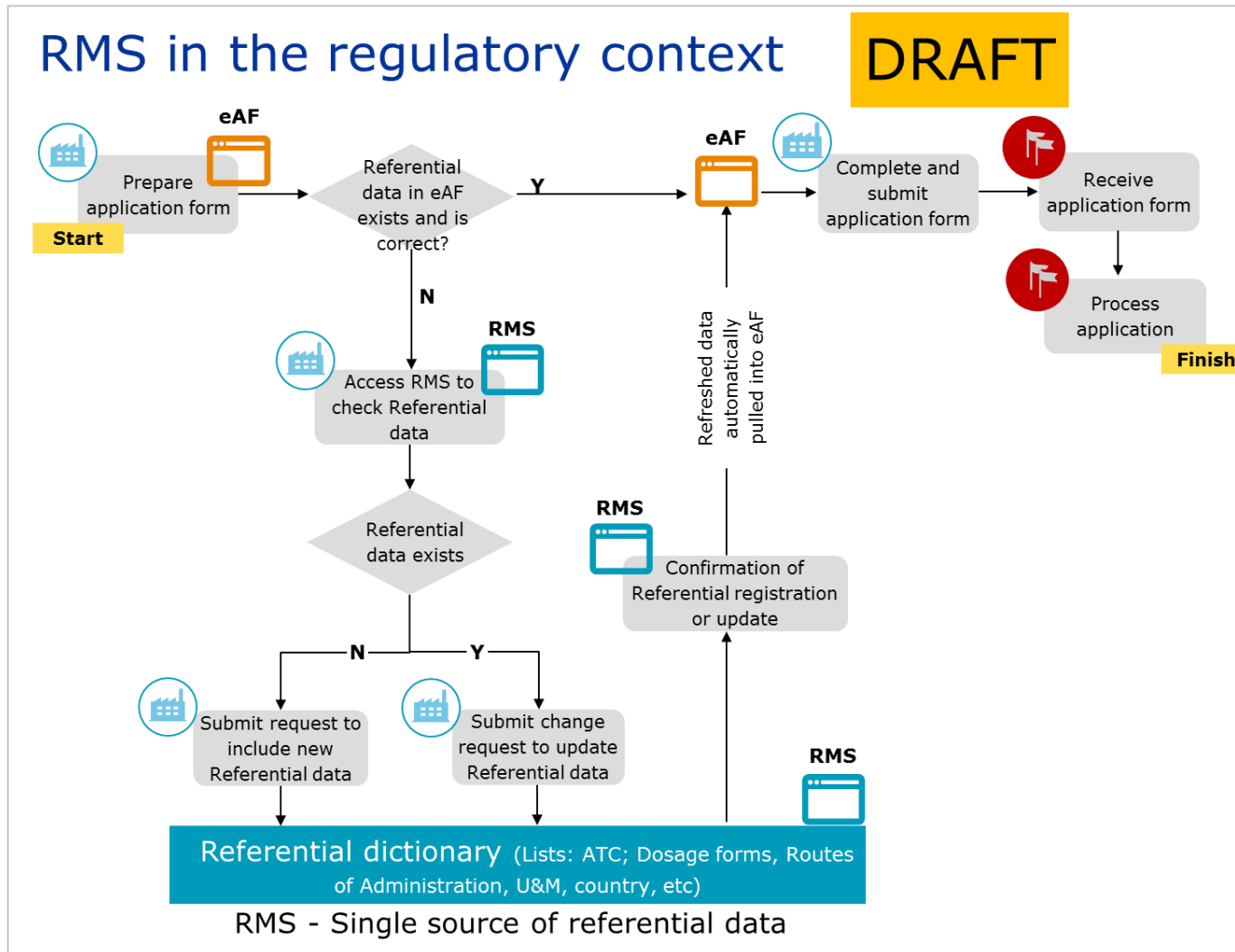
Virtual room capacity: 200

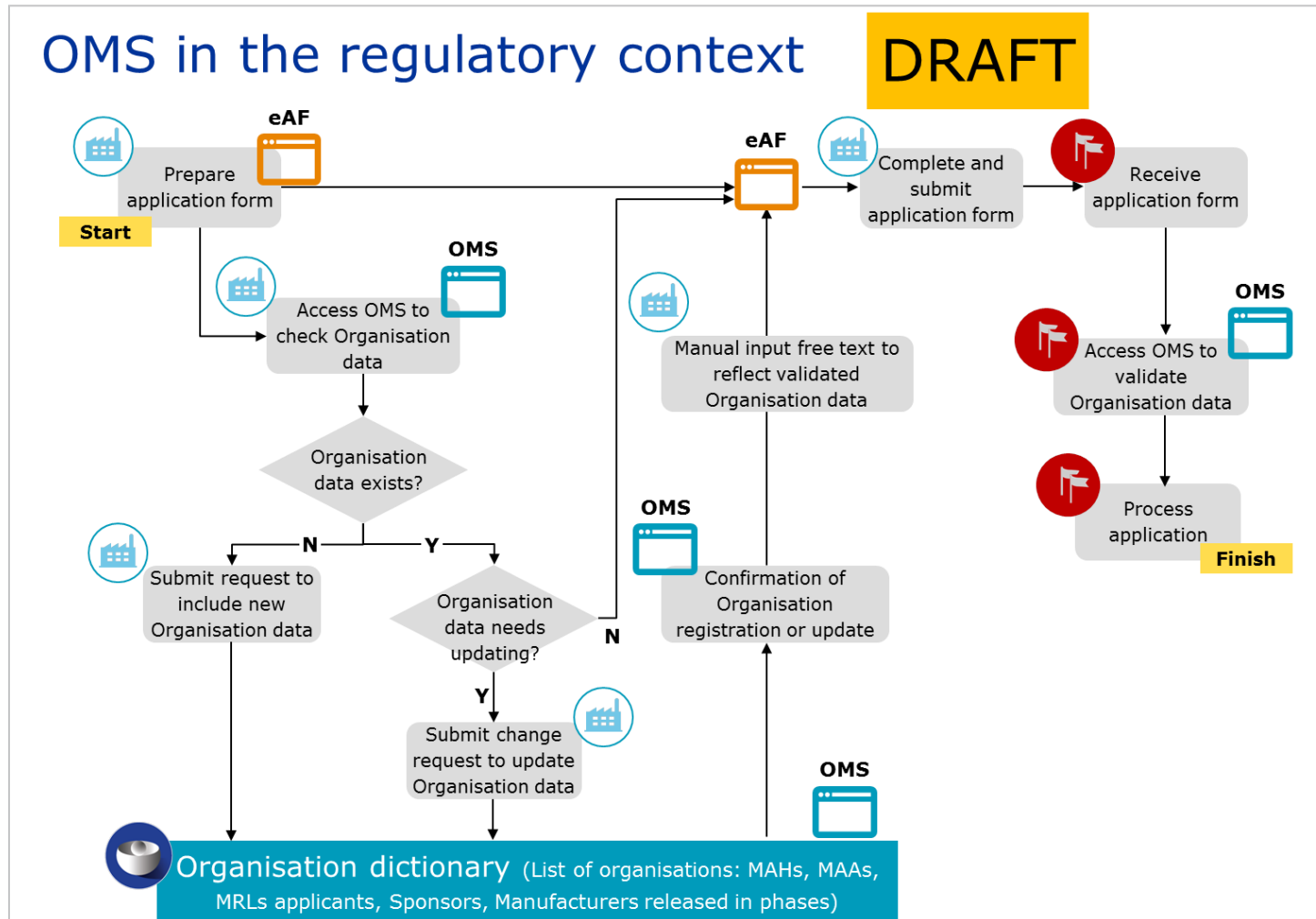
DRAFT agenda:

- Case for SPOR?
- Benefits
- SPOR in eAF / impacts
- OMS in the regulatory context (eAF)
- RMS in the regulatory context (eAF)
- SLAs
- Signpost the relevant documents



Webinar - Using OMS and RMS data in eAF







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Thank you for your attention

Further information

Please send any queries for the change team to:

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